



15/Reg for
Recons c/m
11-9-01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:) Art Unit 1615
)
David D. Mundschenk) Atty. Docket 15050.5.0
)
Serial No. 09/240,455) Examiner: T. Ware
)
Filed: 29 January 1999)
)
For: BUCCAL DELIVERY SYSTEM)

Be
1-17-02

Hon. Commissioner of
Patents and Trademarks
Washington, D.C. 20231

CERTIFICATE	
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By	<u>Marilyn E. Thompson</u>

AMENDMENT

The present Amendment is in response to the Office Action mailed May 8, 2001, the period for response to which has been extended to November 8, 2001 by the accompanying Petition for Extension of Time.

Remarks

Claims 1 and 3-69 are pending.

The rejection of claims 1, 3-4, 9-50 and 52-69 under Section 103(a) is respectfully traversed. Mundschenk '407 is cited for its teaching of the preparation of inactivated bioactive peptides, while Heiber et al. is cited as teaching "buccally administered peptides", and Dondeti et al. and Siegel et al. are cited, essentially, for their inclusion of benzalkonium chloride in delivery compositions (though in each case as "preservatives").

None of the cited references, however, either alone or in suitable combination, teach or suggest the use of a quaternary ammonium salt (such as benzalkonium chloride) to *itself* provide effective permeation of an *inactivated bioactive peptide* into a mucosal surface, and particularly into a mucosal surface of the mouth.